DETAILED ACTION

Applicants communication filed 10/16/09 has been received.

Applicant's election without traverse of a peptide/mimetic/agent comprising Asp-Tyr-Glu-Tyr-Ser in the reply filed on 2/19/09 is acknowledged.

As discussed below, the elected species was found in the prior art and the instant claims are rejected. In accord with section 803.02 of the MPEP the claims have been examined fully with respect to the elected species.

In the reply dated 2/19/09 applicants state that claims 23,25,45-51,53-55 read on the elected species. Claims 24,52,54 read on non-elected species.

Claims 24,52,54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/19/09.

Claims 1-22,26-44 have been cancelled.

Claims 23,25,45-51,53,55 are under consideration.

Claim Objections

Claims 23 is objected to because of the following informalities: claim 23 recites the abbreviation NMDA. The meaning of the abbreviation should be set forth the first time it is used in the claims so as not to confuse it with a tetrapeptide of sequence NMDA. Appropriate correction is required.

Specification

The disclosure is objected to because of the following informalities:

37 CFR 1.821(d) states:

"Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing " in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application."

In the instant case, page 10 lines 31-32, page 13 line 26, and page 15 lines 6-7,21-22 for example recite a sequence for which a SEQ ID NO has been provided but the identifier 'SEQ ID NO:' is not included as required by 37 CFR 1.821(d).

Appropriate correction is required.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 2/19/09 and 1/31/07 have been considered by the examiner.

Priority

It is noted that claim 48 recites that peripheral blood is tested for the presence of anti-NR2 antibodies. A cursory review of the priority documents does not reveal the use of the word peripheral. Since the art cited below qualifies as prior art even if the instant claims receive the

benefit of the provisional application, such issue will not be addressed at this stage of examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50,53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There are 2 different claims labeled as '53'. As such, it is unclear if claim 53 is the first claim 53 or the second claim 53. For purposes of examination the first claim 53 will be referred to as claim 53. The second claim 53 (the one which appears after claim 54) will be referred to as claim 55.

Claims 50 and 53 recite a sequence that contains 2 occurrences of X1 (X1-Trp-X1-Tyr-X2) where X1 represents Asp or Glu. From the claim language it is unclear if the first X1 is Asp if the other X1 must also be Asp. In other words, there is a difference between saying 'X1 represents Asp or Glu' and 'each of X1 independently represents Asp or Glu'. From the language 'X1 represents Asp or Glu' it is unclear if a sequence where the first X1 is Asp and the second X1 is Glu is in the genus.

Although unclear (see 112 2nd) for purposes of examination the first claim 53 will be interpreted as claim 53 and the second claim 53 (the one which appears after claim 54) will be

interpreted as claim 55. Claims 50 and 53 will be interpreted such that each of X1 independently represents Asp or Glu (compare the elected species).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23,25,45,49-50,53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and

knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

Further, to provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include: a) the scope of the invention; b) actual reduction to practice; c) disclosure of drawings or structural chemical formulas; d) relevant identifying characteristics including complete structure, partial structure, physical and/or chemical properties, and structure/function correlation; e) method of making the claimed compounds; f) level of skill and knowledge in the art; and g) predictability in the art.

In the instant case, the claims are drawn to methods of administering an agent that prevents binding of an anti-ds-DNA antibody to an NR2 subunit of an NMDA receptor of a neuron (claim 23,49). Although unclear (see 112 2nd) for purposes of examination the first claim 53 will be interpreted as claim 53 and the second claim 53 (the one which appears after claim 54) will be interpreted as claim 55. Claims 50 and 53 will be interpreted such that each of X1 independently represents Asp or Glu.

(1) Level of skill and knowledge in the art/predictability in the art:

The level of skill in the art is high. There is unpredictability in predicting functional properties of compounds. It is not within the skill of the art to predict any and all compounds that prevent binding of an anti-ds-DNA antibody to an NR2 subunit of an NMDA receptor of a neuron. Further, there is unpredictability in predicting the functional effects of modifications. Claims 50 refers to mimetics and claims 50,53 refer to agents that merely comprise an amino acid of a sequence.

(2) Scope of the invention/Partial structure/disclosure of drawings:

In the instant case, the claims are drawn to methods of administering an agent that prevents binding of an anti-ds-DNA antibody to an NR2 subunit of an NMDA receptor of a neuron (claim 23,49). Although unclear (see 112 2nd) for purposes of examination the first claim 53 will be interpreted as claim 53 and the second claim 53 (the one which appears after claim 54) will be interpreted as claim 55. Claims 50 and 53 will be interpreted such that each of X1 independently represents Asp or Glu.

It is noted that claims 50,53 refer to agents that merely comprise an amino acid of a sequence. Thus any peptide that contains Trp, for example, is a peptide that comprises an amino acid sequence of SEQ ID NO:1 (that is any portion of the sequence). It is noted that claim 51 which is not included in the rejection recites 'comprises Asp-Trp-Glu-Tyr-Ser' which requires the pentapeptide sequence.

Claims 23,25,45,49 merely require an agent. There is no specificity provided as to whether the agent is a peptide, nucleotide, organic molecule, etc. Thus there are many possible structural variations for the agents. Claims 50,53 refer to agents that merely comprise an amino

acid of a sequence. Further, page 10 line 23-26 defines amino acid broadly to include mimetics. Thus any peptide that contains Trp, for example, is a peptide that comprises an amino acid sequence of SEQ ID NO:1 (that is any portion of the sequence). In considering the size of the genus, if any 4 of the amino acids were replaced with any of the 20 naturally occurring amino acids (i.e. mimetics) there are at least 20^4 (i.e. 160000) different compounds. Further, there are many non-natural amino acids and other chemical compounds that could be considered mimetics. As such, the genus is large.

The specification, for example, page 15 recites the elected species. However, the compounds recited represent a small fraction of the possible variety of compounds in the genus. One of skill in the art would not recognize that applicant was in possession of the claimed genus.

There is substantial variability in the genus. Since there are a substantial variety of componds possible within the genus, the examples do not constitute a representative number of species and do not sufficiently describe the genus claimed (see Gostelli above).

(3) Physical and/or chemical properties and (4) Functional characteristics:

Claims 23,49 are drawn to methods of administering an agent that prevents binding of an anti-ds-DNA antibody to an NR2 subunit of an NMDA receptor of a neuron. However, there is no specific disclosed correlation between structure and function. It is unclear what structural elements are required for the recited function. There are no common attributes or characteristics that identify agents that prevent binding of an anti-ds-DNA antibody to an NR2 subunit of an NMDA receptor of a neuron. As such, one of skill in the art would not recognize a core structure, common attributes, or features of the agents. One of skill in the art would not recognize agents outside of those specifically identified. There is no teaching in the specification regarding what

part of the structure can be varied while retaining the ability to prevent binding of an anti-ds-DNA antibody to an NR2 subunit of an NMDA receptor of a neuron. In particular, no common core sequence is taught. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus and that there is a lack of the knowledge in the art regarding which amino acids can vary to maintain the function and thus that the applicant was not in possession of the claimed genus.

(5) Method of making the claimed invention/actual reduction to practice:

The specification, for example, page 15 recites the elected species. However, such compounds are not representative of the instant genus nor do the compounds provide a specific correlation between structure and function such that one could identify any and all agents that prevent binding of an anti-ds-DNA antibody to an NR2 subunit of an NMDA receptor of a neuron.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 23,25,45,49-50,53 is/are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are many. Although the claims may recite some functional characteristics, the claims lack written description because there is no specific disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of compounds identified in the specification tables and/or examples,

the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23,25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaynor et al (US 6,001,964 as cited in IDS 2/19/09).

Gaynor teach methods of treating systemic lupus erythematosis (SLE) ultilizing peptides (abstract). Gaynor teach a method for treating systemic lupus erythematosis in a subject in need of such treatment comprising administering to the subject at least one peptide which binds to an

anti-double stranded DNA antibody (column 2 lines 20-25) and specifically teach the method for humans (column 6 lines 64-66).

Since Gaynor teach administration to those with systemic lupus erythematosis such patients are at risk for lupus-induced cognitive dysfunction as recited in claim 23 since as the name states it is induced by lupus. It is noted that claim 23 recites that the agent prevents binding of an anti-ds-DNA antibody to an NR2 subunit of an NMDA receptor of a neuron. Gaynor teach peptides which bind to an anti-double stranded DNA antibody (column 2 lines 20-25) thus there is a reasonable basis, absence evidence to the contrary, that the claim limitations are met. It is noted that claim 25 refers to the location of a neuron. However, such claim does not require additional steps to be performed. Since Gaynor teach peptides which bind to an anti-double stranded DNA antibody (column 2 lines 20-25) such peptides would have the function as recited in claim 25 absence evidence to the contrary.

Although unclear (see 112 2nd) for purposes of examination the first claim 53 will be interpreted as claim 53 and the second claim 53 (the one which appears after claim 54) will be interpreted as claim 55. Claims 50 and 53 will be interpreted such that each of X1 independently represents Asp or Glu.

Claims 46-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Degiorgio et al (Nature Medicine 'A subset of lupus anti-DNA antibodies cross-reacts with the NR2 glutamate receptor in systemic lupus erythematosis' 2001 v30 pages 1189-93 as cited in IDS 1/31/07).

Degiorgio teach that in systemic lupus erythematosis (SLE) that antibodies against double-stranded DNA are a major contributor to disease (abstract) and correlate with disease

(page 1189 first column). Degiorgio teach that antibodies from lupus patients were isolated and were found to bind dsDNA (page 1190 2nd column, Figure 3). Degiorgio conclude that lupus sera contains antibodies to the NMDA receptors NR2a and NR2b (page 1190 2nd column). As such, Degiorgio teach the active step of claim 46 – determining whether or not a patient has anti-NR2 antibodies. It is noted that claim 46 recites 'wherein the presence of anti-NR2 antibodies indicates that the patient is at risk for lupus-induced cognitive dysfunction'. However, the wherein cause does not result in a manipulative difference or require additional steps to be performed. Further, Degiorgio expressly teach that cerebrospinal fluid of a patient with lupus was found to contain antibodies as well (page 1190 2nd column last paragraph,page 1191 3rd paragraph, Figure 6) thus meeting the limitations as recite in claim 47

Although unclear (see 112 2nd) for purposes of examination the first claim 53 will be interpreted as claim 53 and the second claim 53 (the one which appears after claim 54) will be interpreted as claim 55. Claims 50 and 53 will be interpreted such that each of X1 independently represents Asp or Glu.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23,25,45-51,53,55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaynor et al (US 6,001,964 as cited in IDS 2/19/09) and Degiorgio et al (Nature Medicine 'A subset of lupus anti-DNA antibodies cross-reacts with the NR2 glutamate receptor in systemic lupus erythematosis' 2001 v30 pages 1189-93 as cited in IDS 1/31/07).

Gaynor teach methods of treating systemic lupus erythematosis ultilizing peptides (abstract).

Gaynor does not teach in a single embodiment the administration of the elected peptide nor the administration to the brain. Gaynor does not teach in a single embodiment the determination of whether the patient has anti-NR2 antibodies.

Gaynor teach methods of treating systemic lupus erythematosis (SLE) ultilizing peptides (abstract). Gaynor teach that diagnosis of SLE is difficult without laboratory tests and teach that antibodies directed to double-stranded DNA (dsDNA) are diagnostic of SLE (column 1 lines 20-25). Gaynor teach a method for treating systemic lupus erythematosis in a subject in need of such treatment comprising administering to the subject at least one peptide which binds to an anti-double stranded DNA antibody (column 2 lines 20-25) and specifically teach the method for

humans (column 6 lines 64-66). Gaynor teach various peptides that carry out such function (column 3 lines 60 - column 4 lines 40). Gaynor specifically teach a peptide of sequence Asp-Trp-Glu-Tyr-Ser (claims 9,44, column 9 line 11). Gaynor teach that the peptides neutralize antibodies which are important in the pathogenesis of SLE (column 7 lines 4-10). Gaynor teach that the compositions can be administered using procedures known in the art including a variety of administration modes (column 7 lines 12-20). Gaynor further teach that the peptides can be delivered to the site of action by injection (column 7 lines 30-40).

Since Gaynor teach a method for treating systemic lupus erythematosis in a subject in need of such treatment comprising administering to the subject at least one peptide which binds to an anti-double stranded DNA antibody (column 2 lines 20-25) and specifically teach the method for humans (column 6 lines 64-66) one would be motivated to administer peptides to humans with systemic lupus erythematosis as recited in claim 23. Since Gaynor specifically teach a peptide of sequence Asp-Trp-Glu-Tyr-Ser (claims 9,44, column 9 line 11) and use that specific peptide in Figure 3 one would be motivated to administer the peptide Asp-Trp-Glu-Tyr-Ser thus meeting the limitations recited in claims 53,56. Since Gaynor teach administration to those with systemic lupus erythematosis such patients are at risk for lupus-induced cognitive dysfunction as recited in claim 23 since as the name states it is induced by lupus. It is noted that claim 25 refers to the location of a neuron. However, such claim does not require additional steps to be performed. Since Gaynor teach peptides which bind to an anti-double stranded DNA antibody (column 2 lines 20-25) including the elected peptide such peptides would have the function as recited in claim 25.

Degiorgio teach that in systemic lupus erythematosis (SLE) that antibodies against double-stranded DNA are a major contributor to disease (abstract) and correlate with disease (page 1189 first column). Degiorgio teach that pentatpeptides which have previously been identified mimic the double stranded DNA (abstract). Degiorgio teach that the consensus sequence is present in NMDA receptors NR2a and NR2b (page 1189 fitst column -second column connecting paragraph). Degiorgio teach that antibodies from lupus patients were isolated and were found to bind dsDNA (page 1190 2nd column, Figure 3). Degiorgio conclude that lupus sera contains antibodies to the NMDA receptors NR2a and NR2b (page 1190 2nd column). Degiorgio teach that cerebrospinal fluid of patients with lupus was also tested (page 1190 2nd column last paragraph). Degiorgio teach that cerebrospinal fluid of a patient with lupus contains anti-DNA antibodies (abatract). Degiorgio noted that the antibodies may be produced in the brain or may cross the blood brain barrier (page 1191 paragraph connecting column 1 and 2).

Gaynor teach methods of treating lupus specifically systemic lupus erythematosis (abstract, column 2 lines 20-25). Since Gaynor teach that diagnosis of SLE is difficult without laboratory tests and teach that antibodies directed to double-stranded DNA (dsDNA) are diagnostic of SLE (column 1 lines 20-25) one would be motivated to determine the appropriate patient population by determining patients with the appropriate antibodies. Since Gaynor does not elaborate about which specific antibodies to test one would be motivated to use the teachings of Degiorgio. Thus one would be motivated to identify patients with anti-NR2 antibodies as taught by Degiorgio page 1190 2nd column, Figure 3) thus meeting the limitations of claims 46. One would be motivated to combine the teachings of the prior art to address the problem in the art – the treatment of lupus. Further, since Degiorgio teach that cerebrospinal fluid of patients

with lupus was also tested (page 1190 2nd column last paragraph) one would be motivated to test for antibodies from the cerebrospinal fluid as recited in claim 47. Since Degiorgio noted that the antibodies may be produced in the brain or may cross the blood brain barrier (page 1191 paragraph connecting column 1 and 2) one would be motivated to also test for antibodies from peripheral blood as recited in claim 48. Since Gaynor teach a method for treating systemic lupus erythematosis in a subject in need of such treatment comprising administering to the subject at least one peptide which binds to an anti-double stranded DNA antibody (column 2 lines 20-25) and specifically teach the method for humans (column 6 lines 64-66) one would be motivated to administer peptides to humans with systemic lupus erythematosis as recited in claims 23,49. Since Gaynor specifically teach a peptide of sequence Asp-Trp-Glu-Tyr-Ser (claims 9,44, column 9 line 11) and use that specific peptide in Figure 3 and Degiorgio also recognize such peptide (abstract) one would be motivated to administer the peptide Asp-Trp-Glu-Tyr-Ser thus meeting the limitations recited in claims 50-51,53,56. Gaynor teach that the compositions can be administered using procedures known in the art including a variety of administration modes (column 7 lines 12-20). Gaynor further teach that the peptides can be delivered to the site of action by injection (column 7 lines 30-40). Degiorgio specifically teach that the NR2 receptors are present on neurons in the brain (page 1189 2nd column). Thus one would be motivated to administer the peptides to the brain as recited in claim 45. One would have a reasonable expectation of success since Degiorgio recognize injections to the cortex (page 1190 first paragraph).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Although unclear (see 112 2nd) for purposes of examination the first claim 53 will be interpreted as claim 53 and the second claim 53 (the one which appears after claim 54) will be interpreted as claim 55. Claims 50 and 53 will be interpreted such that each of X1 independently represents Asp or Glu.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 46 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1,19 of U.S. Patent No. 7517657. Although the conflicting claims are not identical, they are not patentably distinct from each other.

7517657 teach detecting the presence of an anti-double stranded DNA antibody in a biological sample by using a specific peptide (claim 1) wherein the detection indicates the subject has systemic lupus erythematosus (claim 19). 7517657 teach the active step of claim 46 – determining whether or not a patient has antibodies. Since the peptide as used in claim 1 of 7517657 is the same as the peptides of the instant invention there is a reasonable basis that the same antibodies are detected as recited in claim 46.

Although unclear (see 112 2nd) for purposes of examination the first claim 53 will be interpreted as claim 53 and the second claim 53 (the one which appears after claim 54) will be interpreted as claim 55. Claims 50 and 53 will be interpreted such that each of X1 independently represents Asp or Glu.

Claims are directed to an invention not patentably distinct from the claims of commonly assigned U.S. Patent No. 7517657 as discussed above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 7517657, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Prior art of Record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Gaynor et al (2005/0214852 as cited in IDS 2/19/09) – like U.S. Patent No. 7517657 Gaynor teach detecting antibodies (claim 24,71).

Vojdani et al (US 2003/0100035) – Vojdani teach peptides comprising DWEYS (section 0040 example 8).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654

/Ronald T Niebauer/
Examiner, Art Unit 1654